THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS and SANOFI-AVENTIS U.S. LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. 07-792 (GMS)
APOTEX INC. and APOTEX CORP.,	)	
Defendants.	)	

PLAINTIFFS' REPLY BRIEF IN SUPPORT OF THEIR MOTION TO ENJOIN THE PARTIES FROM PROSECUTING SECOND FILED, DUPLICATIVE LITIGATION

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INTRODUCTION

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") respectfully submit this reply brief in further support of their motion to enjoin the parties from prosecuting the second filed, duplicative litigation in the Southern District of Florida. To be clear, sanofi-aventis is asking that the Court enjoin *all parties* from pursuing the Florida action, and not to "enjoin Apotex from defending itself" as Apotex mischaracterizes in its opposition brief. *See, e.g.,* D.I. 27 at 1. The Court has both the power and a duty to take such action to prevent the waste of judicial, party, and witness resources and the potential for inconsistent rulings that will result from the parties pursuing identical claims and defenses both here and in Florida. Far from being "unprecedented" as Apotex claims, enjoining the second-filed protective suit in Florida in favor of the first-filed Delaware action is supported by an expansive body of case law in which the courts have applied the first-filed rule to enjoin, transfer, or stay second-filed actions even where both cases were brought by the same plaintiff. And there are no rare or extraordinary circumstances that would support a deviation from the first-filed rule in this case where the convenience of the parties and witnesses, the conservation of limited judicial resources, and even the goals of the Hatch-Waxman Act would be furthered by sanofi-aventis and Apotex litigating their claims and defenses in this Court along with the 15 other ANDA defendants. Apotex simply should not be allowed to game the system to the detriment of sanofi-aventis, the other ANDA first-filers, and the judicial system for its own benefit under the pretense of trying to get inexpensive drugs to market quickly.

ARGUMENT

I. SANOFI-AVENTIS REQUESTS THAT THE COURT ENJOIN *BOTH* SANOFI-AVENTIS AND APOTEX FROM PROSECUTING THE SECOND-FILED FLORIDA ACTION

Apotex's claim that sanofi-aventis is "asking this Court to enjoin Apotex from defending itself in the lawsuit that Sanofi brought against it in Florida" is incorrect. *See* D.I. 27 at 1, 5. Sanofi-aventis's motion, even in its title, clearly states that it is asking the Court to "enjoin the parties"—both sanofi-aventis and Apotex—"from prosecuting the second filed, duplicative action." D.I. 24, 25 at 1, 3 ("enjoin both parties"), 11 ("enjoin both sanofi-aventis and Apotex"), 22 ("the parties must be enjoined"), 23 ("enjoining the parties"). Likewise, there is no support for Apotex's assertion that an injunction will "require the parties to violate the Florida Court's Scheduling Order." *See* D.I. 27 at 2. As sanofi-aventis will also be enjoined, there will be nothing for Apotex to defend itself against in Florida and nothing for the Florida court to schedule or manage. Rather, the parties will pursue their claims and defenses in this Court—the first-filed forum.

II. THE COURT HAS BOTH THE POWER AND A DUTY TO ISSUE AN INJUNCTION IN THIS CASE

The relief sanofi-aventis seeks is not "unprecedented." *See* D.I. 27 at 1. In fact, the law of this District and the Third and Federal Circuits shows that the Court not only has the power to enjoin the parties from prosecuting a second-filed, duplicative action, but also the duty to do so to avoid the senseless waste of judicial, party, and witness resources and to avoid the potential for inconsistent pretrial rulings. D.I. 25 at 12-16; *Triangle Conduit & Cable Co. v. Nat'l Elec. Prods. Corp.*, 125 F.2d 1008, 1009 (3d Cir. 1942), *cert. denied*, 316 U.S. 676 (1942) ("[I]t was the duty of the court first obtaining jurisdiction to enjoin the prosecution of the subsequent proceedings in the other court."). As explained in sanofi-aventis's opening brief, courts have not

only applied the first-filed rule to enjoin second-filed actions, but have even done so where both actions were brought by the same plaintiff.[1] *See Bamdad Mech. Co., Ltd. v. United Techs. Corp.*, 109 F.R.D. 128, 132 (D. Del. 1985); *Old Charter Distillery Co. v. Cont'l Distilling Corp.*, 59 F. Supp. 528, 530 (D. Del. 1945). The rationale supporting an injunction is the same regardless of who brings the second suit—if the parties are allowed to prosecute the second-filed action, two courts will waste time and resources by managing identical discovery and conducting the very same pretrial proceedings, while the parties and the witnesses are forced to do the same. *See* D.I. 25 at 11-13. These issues are even more pressing here, as regardless of where the Apotex action proceeds, sanofi-aventis's claims against the other 15 ANDA defendants[2] must go forward in this District.[3]

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[1] In another attempt to make an end run around the first-filed rule, Apotex states that "MDL rules specifically provide that cases are to proceed … while a transfer motion is pending." *See* D.I. 27 at 2. But there is nothing in the JPML rules that infringes on the inherent power of a court to enjoin a later-filed duplicative action. Rather the rules merely provide that district court cases are not ***automatically*** stayed pending a JPML ruling. Thus, the Court is free to enjoin the parties just as it would be were there no JPML motion pending.

[2] Since filing its motion, sanofi-aventis filed on March 14, 2008 a fourth action in this Court against two additional ANDA filers, Wockhardt Limited and Wockhardt USA, Inc., for infringement of the '940 patent in *Sanofi-aventis et al. v. Wockhardt Limited et al.*, No. 08-150 (GMS). This action has been designated a related case to the three previously pending Uroxatral® actions pending in this District and assigned to the same Judge.

[3] Apotex's contention that continuing with the Florida action "will not waste judicial resources and will not result in duplicative discovery" defies logic. *See* D.I. 27 at 3. Regardless of where sanofi-aventis's claims against Apotex proceed, discovery for the three related actions against the other 15 ANDA defendants will proceed in Delaware for infringement of the same patents at issue in this case based on ANDA filings for the same reference product. If the parties are not enjoined from prosecuting the Florida action, both this Court and the Florida court will be forced to become experts in the technology at issue, manage discovery, and conduct pretrial proceedings, including claim construction, on identical or similar issues. Moreover, as the issues with respect to sanofi-aventis's activities concerning the reference product Uroxatral® and the patents-in-suit are identical, failure to enjoin the Florida action would lead to multiple

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Apotex fails in its attempts to distinguish this action from this substantial body of precedent. For example, Apotex argues that the *Bamdad* decision does not apply because there is no danger of inconsistent rulings here and that the Court may merely adopt any findings by the Florida court. *See* D.I. 27 at 6. This argument ignores the existence of the other three related cases in addition to the two Apotex actions. None of the 15 other ANDA defendants in those actions are participating in the Florida case. Consequently, any ruling by the Florida court on claim construction, for example, would not have the input of those defendants. Therefore, to the extent that this Court and the Florida court issue different claim constructions, the same asserted claims may have different meanings for different defendants. This potential for inconsistent results, as well as the waste in judicial and party resources in reaching them, can be avoided by simply requiring sanofi-aventis and Apotex to adjudicate their claims and defenses in Delaware with the other ANDA defendants.

Apotex also argues that sanofi-aventis is not entitled to injunctive relief because it could raise the issues presented in this motion in the Florida court. *See* D.I. 27 at 2-3. As an initial matter, this position is contradicted by the case law discussed above and in sanofi-aventis's opening brief where the courts have issued injunctions. And Apotex does not cite to any cases in support of its argument, instead relying on quotations from the Wright & Miller treatise. Even that treatise, the portion which Apotex quotes, but does not address in its argument, supports an injunction in this case—it states that an injunction may be granted if it can be shown "that the balance of convenience favors deciding the entire controversy in the court

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depositions of witnesses concerning the development of Uroxatral® and prosecution of the patents-in-suit, as well as all regulatory and marketing issues on which defendants may seek discovery.

that is asked to restrain the parties in the other proceeding." *See* D.I. 27 at 4 n.2 (citing 11 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 2942 (2008)). That is precisely the situation here. There are five related Uroxatral® cases involving 17 ANDA defendants in two different courts, four in Delaware, including the present case, and one in Florida. These cases involve the same legal issues concerning the validity and infringement of the '491 patent and/or '940 patent. It is beyond dispute that enjoining the parties from prosecuting the Florida action will not only prevent inconsistent rulings, but will also conserve judicial resources, avoid duplicative discovery, and prevent witnesses from having to appear for deposition on multiple occasions. Thus, the balance of convenience even under the authority cited by Apotex favors enjoining the Florida action.

III. THE FIRST-FILED RULE APPLIES TO CONSERVE JUDICIAL RESOURCES AND PREVENT INCONSISTENT RULINGS EVEN WHERE PLAINTIFF BRINGS BOTH SUITS

Sanofi-aventis does not place "undue reliance" on the first-filed rule in asking the Court to enjoin the second-filed Florida action. *See* D.I. 27 at 5. This principle of comity directly supports the relief requested and forms the basis of the Court's duty to issue an injunction to conserve judicial resources and prevent potentially inconsistent rulings. This District and others have repeatedly applied the first-filed rule in ANDA cases where plaintiffs brought both actions to require the parties to litigate their claims and defenses in the first-filed forum.[4] D.I. 25 at 16-18. In doing so, the courts have expressly recognized the need for second-

[4] *See e.g., Celgene Corp. v. Abrika Pharms., Inc.*, Civ. No. 06-741-SLR, slip op. at 1 (D. Del. July 18, 2007); *Celgene Corp. v. Abrika Pharms., Inc.*, No. 06-5818 (SDW), 2007 WL 1456156, at *1, 4 (D.N.J. May 17, 2007); *Abbott Labs. v. Andrx Corp.*, Case 00-6520-CV-SH, Transcript of Scheduling Conference (S.D. Fla. July 10, 2000) at 12-13; *PDL Biopharma, Inc. v. Sun Pharm. Inds., Ltd.*, No. 07-11709, 2007 WL 2261386, at *2 (E.D. Mich. Aug. 6, 2007); *Schering Corp. v. Caraco Pharm. Labs., Ltd.*, No. 06-14386, 2007 WL 1648908, at *3 (E.D. Mich. June 6, 2007); *Aventis Pharma S.A. v. Sandoz Inc.*, (Continued . . .)

filed "protective suits" in ANDA litigations due to the ambiguities concerning jurisdictional challenges under the Hatch-Waxman Act and the serious risks patentees face if their first-filed actions are dismissed—namely the loss of the 30-month stay of generic approval while a patent litigation is pending. *See e.g. PDL*, 2007 WL 2261386, at *2; *Abbott*, 2006 WL 850916, at *8.

It was this uncertainty and Apotex's refusal to timely consent to jurisdiction in this Court which forced sanofi-aventis to sue Apotex in Florida. This fact is far from "irrelevant"—sanofi-aventis chose to sue Apotex in the District of Delaware where its claims against, at that time, 13 other ANDA defendants were pending so that all of the patent infringement claims concerning generic versions of Uroxatral® could be litigated in one court in a coordinated manner. *See* D.I. 27 at 4. Nor is this assertion "factually questionable" as Apotex contends. *Id.* Sanofi-aventis stated explicitly in its Florida complaint that its ***only reason*** for filing the action was because Apotex had not yet consented to jurisdiction and that "[i]n the event Defendants are unsuccessful in any such [jurisdictional] challenge, Plaintiffs will dismiss this action." *See* D.I. 25 at 9, Ex. O ¶ 19. Sanofi-aventis never served the Florida complaint. It was Apotex who decided to answer it just one business day before consenting to jurisdiction in this Court and has since refused to agree to its dismissal.[5]

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No. 06-3671 (MLC), 2007 WL 1101228, at *3 (D.N.J. Apr. 10, 2007); *Abbott Labs. v. Mylan Pharms, Inc.*, No. 05 C 6561, 2006 WL 850916, at *8 (N.D. Ill. Mar. 28, 2006).

[5] Apotex tries to justify its end-run around the first-filed rule by arguing that if sanofi-aventis was "concerned about jurisdiction in Delaware, it could have sued Apotex here anytime during the first 24 days of that 45 day period, and still have sufficient time to file suit in Florida after" Apotex answered, if Apotex had challenged personal jurisdiction. D.I. 27 at 5. This position defies logic and is contrary to the purpose of the Hatch-Waxman Act in providing a 45-day period of time for innovator companies to bring suit, which is to allow the patentee sufficient time to determine whether the proposed generic product infringes the patent. Congress did not provide a 45-day period so that jurisdictional challenges could be resolved. If that were the case, every generic company
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Instead of addressing the extensive body of law that supports a patentee's need to file protective actions under these circumstances, Apotex relies on a handful of cases that are neither binding on the Court nor persuasive authority to support its position. For example, Apotex cites *Aventis Pharma Deutschland GMBH v. Lupin Ltd.*, 403 F. Supp. 2d 484, 489 (E.D. Va. 2005), to argue that the first-filed rule does not apply when the plaintiff files both actions. *See* D.I. 27 at 7. This case, however, is readily distinguished from *Lupin*. First, the *Lupin* court based its ruling on the erroneous holding that the first-filed rule was limited to the race-to-the courthouse situation. *Lupin*, 403 F. Supp. 2d at 489-90. As discussed in sanofi-aventis's opening brief, D.I. 25 at 16-18, district courts post-*Lupin*, such as the *PDL*, *Celgene*, and *Abbott* courts, have recognized the need for filing ANDA "protective" suits and have expressly rejected *Lupin*'s limitation on the first-filed rule. *See e.g., Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, No. 1:07-cv-993, 2007 WL 4284877, at *2 (W.D. Mich. Dec. 3, 2007) (refusing to apply the *Lupin* court's "mechanical limitation" and noting "the harsh outcome should [the first-filed forum] dismiss the cause of action after the 45 day filing period, the extraordinary circumstances of the case weigh in favor of granting the stay" of the second-filed action). Second, defendants in *Lupin* contested jurisdiction in the first-filed forum; here, Apotex has confirmed that it will not contest jurisdiction in this Court. *Compare Lupin* 403 F. Supp. 2d at 488 *to* D.I. 7 ¶ 8, 9. Third, unlike the situation in *Lupin* as expressly recognized by that court, here there are three additional related actions against 15 other ANDA defendants pending in the

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would wait until the end of the 45-day period to contest jurisdiction, thereby ensuring that the jurisdictional question would not be resolved until after the 45-day period ended and the patentee lost the right to the 30-month stay. Moreover, there is no guarantee that Apotex would not have sought and received an extension, which are routinely granted, to file its answer after the 45-day period had expired.

first-filed forum that will proceed regardless of where the Apotex case is tried. Finally, in finding that the first-filed rule was inapplicable, the *Lupin* court stated that the plaintiffs in that case did "not explain why or if the [Hatch-Waxman Act] requires such a 'protective measure' [as a second-filed suit]." *Lupin*, 403 F. Supp. 2d at 490. In contrast, sanofi-aventis has made clear that its sole reason for filing in Florida was to protect its right to a 30-month stay in the event that this action was dismissed for lack of jurisdiction. *See* D.I. 25, Ex. O ¶ 19.

Apotex also relies on a letter opinion from *Adam Respiratory Therapy, Inc. v. Mut. Pharm. Holdings Co.*, Civil Action No. 06-4700 HAA, slip op. (D.N.J. Nov. 16, 2006), to support its position. *See* D.I. 27 at 7. The primary concern of the *Adams* court, however, was judge shopping. Here, sanofi-aventis was not judge shopping but merely trying to ensure that its claims would go forward if Apotex successfully challenged personal jurisdiction in this Court. Sanofi-aventis's intention was clear—it sought Apotex's consent to jurisdiction here prior to filing the Florida action and never served the Florida complaint on Apotex. *See* D.I. 25, Ex. O ¶ 19; *Celgene*, 2007 WL 1456156, at *4 (noting a clear indication that plaintiffs preferred the first-filed forum as they did not serve the second-filed complaint). Furthermore the *Adams* court, like the court in *Lupin*, did not appreciate the specific jurisdictional issues relevant to ANDA actions and the serious consequences patentees face due to the ambiguities in the statute and case law concerning those issues if they do not file second, "protective" suits in certain circumstances. Finally, the *Adams* opinion has not been followed in the issuing forum. *See Celgene*, 2007 WL 1456156, at *4.[6]

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[6] The other case cited by Apotex, *Employers Reinsurance Corp. v. MSK Ins., Ltd.*, is inapposite. No. Civ.A.01-2608-CM, 2003 WL 21143105, at *6 (D. Kan. Mar. 31, 2003). That case did not involve an ANDA litigation, but a declaratory judgment action on a breach of contract claim. Moreover, the court declined to apply the first-filed rule

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IV. NEITHER THE FLORIDA SCHEDULE NOR THE HATCH-WAXMAN ACT JUSTIFY A DEPARTURE FROM THE FIRST-FILED RULE

Apotex advocates a departure from the first-filed rule in this case because of the Florida schedule and based on its completely unsupported belief that the Hatch-Waxman Act demands that ANDA cases be adjudicated as quickly as possible without regard to any interests other than speed. In fact, courts only favor a second-filed forum in "rare or extraordinary circumstances," such as those involving "inequitable conduct, bad faith, or forum shopping," *EEOC v. Univ. of Pa.*, 850 F.2d 969, 972 (3d Cir. 1988), *aff'd on other grounds*, 493 U.S. 182 (1990). Apotex does not allege, because it cannot, that sanofi-aventis's conduct in filing the Florida action involved inequitable conduct, bad faith, or forum shopping. As discussed above, sanofi-aventis only filed the Florida action because Apotex did not timely consent to jurisdiction, and sanofi-aventis always intended to dismiss the case if Apotex was unsuccessful in challenging this Court's jurisdiction. Moreover, Apotex has not shown that either the convenience of the parties or witnesses would favor proceeding in Florida. In fact, both would be supported by having all claims concerning the patents-in-suit and Uroxatral® decided in one court on a coordinated schedule to avoid duplicative discovery and other pretrial proceedings.

Instead, Apotex takes the position that ANDA cases must be decided as quickly as possible and that proceeding in Florida will lead to the fastest resolution. *See* D.I. 27 at 4. As an initial matter, there is nothing in the Hatch-Waxman Act itself or the case law construing it that demands that cases be resolved as quickly as possible without regard to any other

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because it found that the first-filed action was a preemptive strike, a fact not present here. *Id*.

considerations.[7] Rather, in implementing the Act, "Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1327 (Fed. Cir. 2005). Thus, the Act recognized the importance of patentees' rights by making the filing of an ANDA and paragraph IV certification an act of infringement. Further, the Act expressly provides a 30-month period in which the litigation should proceed in order to afford the parties adequate time to litigate any infringement action in an orderly fashion without any damages issues or questions of emergency injunctions while there is a stay of FDA approval. 21 U.S.C. § 355(j)(5)(B)(iii); *Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 344 (D.N.J. 2003); *Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 146 F. Supp. 2d 572, 578 (D.N.J. 2001). Requiring innovators such as sanofi-aventis to conduct duplicative litigation in multiple fora, as Apotex seeks to do, would result in increased costs to innovators, reducing their incentives to bring new drugs to market and frustrating a key purpose of the Hatch-Waxman Act.

In any event, Apotex's conduct in the litigation to date in both Florida and this Court demonstrates that the availability of low-cost drugs is not its concern. Apotex's gambit of aggressively pressing the Florida case is motivated by the potential for significant financial gain to Apotex if it is able to enter the market with a generic copy of sanofi-aventis's Uroxatral® product without competition from the other ANDA defendants. In fact, two other generic defendants call Apotex out for trying to place itself on unequal footing compared to the other

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[7] To support its argument, Apotex cites to *Boehringer Ingelheim Corp. v. Shalala*, 993 F. Supp. 1, 3 (D.D.C. 1997) and *Schering Corp. v. Sullivan*, 782 F. Supp. 645, 652 (D.D.C. 1992). This reliance is misplaced. Neither case involved a patentee suing an ANDA filer under the Hatch-Waxman Act.

first-filer defendants with respect to the 180-day exclusivity period and characterize Apotex's actions as "contrary to the Hatch-Waxman Act …." D.I. 25, Ex. DD at 9. Under these circumstances, allowing duplicative actions to proceed in parallel would provide Apotex with a powerful incentive to continue to delay resolution of this action, thereby in fact reducing the potential for the generic competition that Apotex purports to espouse. Enjoining the Florida action will place all first-filer ANDA defendants on equal footing. As other defendants here have noted, this is a primary purpose of the Act. Indeed, resolution of sanofi-aventis's claims will best be expedited under the Hatch-Waxman Act through cooperation between sanofi-aventis and all 17 ANDA defendants in a single forum.

Apotex's argument is also erroneously based on the claim that the Florida action is well under way and that the Florida court has devoted substantial resources to the case. *See* D.I. 27 at 1, 3. In reality, the Florida case is in its infancy. The parties have exchanged initial disclosures, and while Apotex has served document requests and interrogatories, sanofi-aventis has sought a protective order to stay all non-venue related discovery pending rulings on the parties' various pending motions. Sanofi-aventis will begin to produce documents in the Florida action this week, but it is also producing those same documents to the other defendants in Delaware that have agreed to treat the production under the protective order terms agreed to by the parties to date. Moreover, the Florida court has not yet held its initial case management conference[8] and does not appear to have invested substantial resources in the case as various

[8] Sanofi-aventis's representations concerning the lack of a case management conference with the Florida Court are not misleading. *See* D.I. 27 at 3 n.1. The Florida court denied the parties' motions to submit their Rule 16 conference reports and proposed schedules as moot in light of its previous scheduling order (which ordered the parties to make those submissions). While that scheduling order is still in force, the parties have in fact not had a case management conference with the Court to set additional pretrial dates, such as for

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motions are still pending and no technical issues concerning the patents-in-suit, the reference product, or the proposed generic product have been presented by the parties. Thus, any suggestion by Apotex that the Florida case is proceeding much more expeditiously or that the Florida court has devoted substantial efforts is incorrect and, in any event, significantly outweighed by the interests in conserving judicial resources on the whole and avoiding duplicative discovery as discussed above.[9]

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expert discovery and *Markman* proceedings, or discovery limitations. Sanofi-aventis have moved the Florida court for a status conference to discuss these issues and the various pending venue motions.

[9] Likewise, given the early stages of the Florida action, this motion is timely, contrary to Apotex's suggestion. *See* D.I. 27 at 1. Moreover, from the time that sanofi-aventis filed the Florida complaint, Apotex knew sanofi-aventis's position that the Delaware case should go forward. *See* D.I. 25, Ex. O ¶ 19.

CONCLUSION

For the foregoing reasons, sanofi-aventis requests that the Court enjoin sanofi-aventis and Apotex from prosecuting the second-filed, duplicative Florida action.

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Dated: April 3, 2008
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CERTIFICATE OF SERVICE

I hereby certify that on April 3, 2008 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to:.

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